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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,899	09/28/2001	Markku Koulu	2630-111	5535

6449 7590 10/07/2003

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1632	6

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,899	KOULU ET AL.	
	Examiner	Art Unit	
	Robert M Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 4-6, drawn to treating a person at increased risk of developing atherosclerosis due to a substitution of proline for wild-type leucine at position 7 of the signal peptide NPY comprising administering a pharmaceutical agent that counteracts the influence of the mutated NPY gene by modulating its synthesis, secretion, or metabolism.

Group II, claim(s) 4-6, drawn to treating a person at increased risk of developing atherosclerosis due to a substitution of proline for wild-type leucine at position 7 of the signal peptide NPY comprising administering a pharmaceutical agent that counteracts the influence of the mutated NPY gene by modulating the synthesis, secretion, or metabolism of a wild-type NPY gene in the same person.

Group III, claim(s) 4-5, drawn to treating a person at increased risk of developing atherosclerosis due to a substitution of proline for wild-type leucine at position 7 of the signal peptide of NPY comprising administering a pharmaceutical agent that counteracts the influence of the mutated NPY gene by interacting with specific NPY receptors.

Group IV, claim(s) 7, drawn to treating a person at increased risk of developing atherosclerosis due to a substitution of proline for wild-type leucine at position 7 of the signal peptide of NPY comprising subjecting the person to specific gene therapy aimed to repair the mutated NPY sequence.

Group V, claim(s) 8-10, drawn to treating diabetic person at increased risk of developing diabetic retinopathy due to a substitution of proline for wild-type leucine at position 7 of the signal peptide NPY comprising administering a pharmaceutical agent that counteracts the influence of the mutated NPY gene by modulating its synthesis, secretion, or metabolism.

Group VI, claim(s) 8-10, drawn to treating a diabetic person at increased risk of developing diabetic retinopathy due to a substitution of proline for wild-type leucine at position 7 of the

signal peptide NPY comprising administering a pharmaceutical agent that counteracts the influence of the mutated NPY gene by modulating the synthesis, secretion, or metabolism of a wild-type NPY gene in the same person.

Group VII, claim(s) 8-9, drawn to treating a diabetic person at increased risk of developing diabetic retinopathy due to a substitution of proline for wild-type leucine at position 7 of the signal peptide of NPY comprising administering a pharmaceutical agent that counteracts the influence of the mutated NPY gene by interacting with specific NPY receptors.

Group VIII, claim(s) 11, drawn to treating a diabetic person at increased risk of developing diabetic retinopathy due to a substitution of proline for wild-type leucine at position 7 of the signal peptide of NPY comprising subjecting the person to specific gene therapy aimed to repair the mutated NPY sequence.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Based on the actions of the agents in Groups I-VIII, we are assuming that the agents are separate and distinct, as each of the effects that the agents cause is different.

Furthermore, given that the specification provides no definition for the agent, each Group (I-VIII) may encompass multiple distinct inventions, so further restriction may be required.

The special technical feature shared by Groups I and II is treating a person at increased risk of developing a disease, based on a single nucleotide polymorphism of the signal peptide of NPY, that of an amino acid 7 mutation from Leucine to Proline in the signal polypeptide. However, these two Groups lack a single general inventive concept, because Group I is concerned with altering expression of the mutant gene, while Group II is concerned with altering the expression of a wild-type gene in a heterozygous host. To do this, the mutant gene's effect must be lessened. In order to lessen this effect through expression of the mutant gene, the artisan would lower the expression of the mutant gene, while to lessen the effect of the mutant gene

through expression of the wild-type gene, the artisan would increase expression of the wild-type gene. Group III does not share a single general inventive concept with that of Groups I and II, because, while Groups I and II aim to alter the expression of the person's endogenous NPY genes, Group III seeks to alter the effect of the expression of such genes through binding the receptors for NPY, thereby interfering with the action of the endogenous gene-expressed proteins. Group IV does not share a single general inventive concept with that of Groups I-III, because Groups I-III seek to alter the effects of the person's endogenous genes, while Group IV seeks to alter the genetic composition of the person's endogenous genes. Groups V-VIII do not share a single general inventive concept with Groups I-IV, because Groups V-VIII are concerned with the treatment of diabetic retinopathy in people with diabetes, while Groups I-IV are concerned with the treatment of a completely different disease, atherosclerosis. Furthermore, until the discovery by applicant, there was no known relation between increased risk for diabetic retinopathy in type 2 diabetic patients and atherosclerosis in people in general. Groups V and VI do not share a single general inventive concept because Group V is concerned with altering expression of the mutant gene to treat diabetic retinopathy, while Group VI is concerned with altering the expression of a wild-type gene in a heterozygous host. Group VII does not share a single general inventive concept with that of Groups V and VI because while Groups V and VI aim to alter the expression of the person's endogenous NPY genes, Group III does not seek to such expression, but seeks to alter the effect of the gene-expressed proteins through interacting with the person's endogenous NPY receptors. Group VIII does not share a single general inventive concept with that of Groups V-VII because Groups V-VII seek to alter the effect of the

person's endogenous genes, while Group VIII seeks to alter the composition of the person's endogenous genes.

Because Groups I-VIII are separate and distinct inventions that do not fall within the scope of 37 C.F.R. § 1.475 (b) or (d), i.e., they represent separate products used in separate processes, a lack of unity is found, and restriction is deemed proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (703) 305-4460. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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